



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/600,673 | 07/20/2000 | BRUCE PAUL DAGGY | C75087 | 9337 |

7590 04/20/2005

DARA L DINNER
SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY UW2220
709 SWEDELAND ROAD
KING OF PRUSSIA, PA 19406-0939

EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,673

Applicant(s)

DAGGY ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed Dec. 23, 2004 is acknowledged.

Claims 19-34 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The rejection of claims 19-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

4. The rejection of claims 19-22, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah (Shah et al, U.S. Patent 4,671,823; issued 06/09/1987) is withdrawn in view of the amendment, where the claims include that the active step is the administration of an amount of methylcellulose effective for reducing the incidence of colorectal cancers in a human.

5. The rejection of claims 19-21, 25-29, 33 and 34 under 35 U.S.C. 102(b) as being anticipated by Folino et al (Folino, M. et al, J. Nutr. 125: 1521-1528, 1995) is withdrawn in view of the amendment, where the claims include that the active step is the administration of an amount of methylcellulose effective for reducing the incidence of colorectal cancers in a human,

Art Unit: 1642

because Folino appears to teach away from the use of methylcellulose for the reduction of cancer incidence.

6. The rejection of claims 19-21, 25-29, 33 and 34 under 35 U.S.C. 103(a) as being unpatentable over Folino et al (supra) in view of Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) is withdrawn in view of the amendment, where the claims include that the active step is the administration of an amount of methylcellulose effective for reducing the incidence of colorectal cancers in a human, because Folino appears to teach away from the use of methylcellulose for the reduction of cancer incidence.

7. The rejection of claims 19-21 and 27-29 under 35 U.S.C. 103(a) as being unpatentable over Folino et al (supra) in view of either Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) or Alabaster et al (Alabaster, O. et al., Cancer Letters, 75: 53-58, 1993; cited in the IDS) is withdrawn in view of the amendment, where the claims include that the active step is the administration of an amount of methylcellulose effective for reducing the incidence of colorectal cancers in a human, because Folino appears to teach away from the use of methylcellulose for the reduction of cancer incidence.

Claim Rejections Maintained:

8. Claims 19-34 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dressman (Dressman et al, U.S. Patent 5,789,393 issued 08/04/1998; effective filing date 02/21/1992) for the reasons of record.

Applicants' arguments have been carefully considered, but fail to persuade. Applicants appear to be arguing limitations that do not appear in the claims. The presently claimed inventions are drawn to methods comprising the administration of methylcellulose in an amount effective for reducing the incidence of colorectal cancer, or breast cancer (claims 27-34). The amounts recited in the claims and taught in the specification also happen to be the amounts that are taught by Dressman. Applicants point to passages in Dressman concerning the viscosity grade of cellulose ether compositions contemplated to be used by Dressman, and argues that the approved products of methylcellulose on the US market are in a range that is significantly below what is contemplated for use by Dressman. However, the instant claims are not limited to any specific viscosity grade of methylcellulose. Therefore, because Dressman teaches that active step of the claimed methods, Dressman teaches a method that is the same as that claimed. Applicants have also argued that the purpose of Dressman's method, that of lipid lowering is different from the purpose of the instant methods. However, this argument is not persuasive, because the active steps of Dressman appear to be the same as the active steps of the instant methods. Therefore, Dressman's method will accomplish the purpose of the instant methods.

Dressman teaches pharmaceutical dosages of compositions comprising methylcellulose that are useful for administration to humans for the reduction of serum lipid levels and or attenuation of postprandial rise in blood glucose levels. Therefore, Dressman teaches methods comprising the administration to humans of compositions comprising methylcellulose, which is an active step that is the same as the active step of the claimed methods. Dressman teaches administration of 10g/day, 20g/day and 30gm/day (col. 31, lines 32-41). Dressman teaches a methylcellose composition that comprises a sugar (col. 15, lines 32-35), that comprises gelatin

Art Unit: 1642

(col. 13, lines 59-60) and wherein the composition is administered as a rapidly disintegrating tablet (col. 15, lines 35-36). Therefore, Dressman teaches methods that are the same as that claimed.

12. Claims 19-23, 25-31, 33 and 34 remain rejected under 35 U.S.C. 103(a) as being anticipated by Dressman (Dressman et al, U.S. Patent 5,789,393 issued 08/04/1998; effective filing date 02/21/1992) in view of Durlach (U.S. Patent 4,232,054, issued 11/4/1980) for the reasons of record.

Applicants' arguments have been carefully considered, but fail to persuade. Applicants argue that because neither Dressman nor Durlach teach the same purpose for the administration of methylcellulose as the stated purpose of the claimed methods that the combination of Dressman and Durlach fails to render the claimed inventions unpatentable. In response to applicant's argument that neither Dressman nor Durlach teach methods for reducing the incidence of cancer, the fact that applicants have recognized another advantage for combining methylcellulose with wheat bran fiber cannot be the basis for patentability. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The combination of Dressman and Durlach provides the active steps of the claimed methods. Therefore, the combination of Dressman and Durlach render the claimed inventions unpatentable over the prior art.

The claimed methods read on methods comprising the administration of methylcellulose in combination with wheat bran.

Dressman teaches pharmaceutical dosages of compositions comprising methylcellulose that are useful for administration to humans for the reduction of serum lipid levels and or attenuation of postprandial rise in blood glucose levels. Therefore, Dressman teaches methods comprising the administration to humans of compositions comprising methylcellulose, which is an active step that is the same as the active step of the claimed methods. Dressman teaches administration of 10g/day, 20g/day and 30gm/day (col. 31, lines 32-41). Dressman teaches a methylcellulose composition that comprises a sugar (col. 15, lines 32-35), that comprises gelatin (col. 13, lines 59-60) and wherein the composition is administered as a rapidly disintegrating tablet (col. 15, lines 35-36).

Dressman fails to teach methods comprising the administration of a combination of methylcellulose and wheat bran. However, Durlach teaches that a wheat bran composition associated to a metallic proteinate such as calcium caseinate is useful to prevent the effect of loss of protein and minerals that accompanies the administration of fibers.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the methylcellulose compositions of Dressman with those of Durlach and used the combined composition in a methods comprising the administration of methylcellulose and wheat bran, because Durlach teaches the benefits of using a nutritive fiber such as wheat bran associated with a metallic proteinate for the purpose of counteracting one of the side effects of fiber administration.

Conclusion

No claim is allowed.

Art Unit: 1642

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
April 18, 2005


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER